



Dkt. #702-A-US

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Gary K. SCHWARTZ
U.S. Serial No.: 10/693,301
Filed : October 24, 2003
For : SCREENING, QUANTITATION AND IDENTIFICATION
OF ACTIVE INGREDIENTS IN NATURAL PRODUCTS

Law Offices of Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, NY 11357

December 11, 2003

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir/Madam:

INFORMATION DISCLOSURE STATEMENT

In accordance with his duty of disclosure under 37 C.F.R. §1.56, Applicant would like to direct the Examiner's attention to the following references which are listed below on Form PTO/SB/08B (**Exhibit A**), with each individual reference further attached as **Exhibit 1** through **23**.

1. L. Zhang, L. Yang, X. Zheng "A study of helicobacterium pylori and prevention and treatment of chronic atrophic gastritis", J. Tradit. Chin. Med. No. 17: 3-9, 1997. [**Exhibit 1**]
2. L.Q. Yang, M. Singh, E.H. Yap, G.C. Ng, H.X. Xu, and K.Y. Sim, "In vitro response of Blastocystis hominis against traditional Chinese medicine", J. Ethnopharmacol 55: 35-42, 1996. [**Exhibit 2**]
3. S.G. Franzblau and C. Cross, "Comparative in vitro antimicrobial activity of Chinese medicinal herbs. J. Ethnopharmacol", 15: 279-288, 1986. [**Exhibit 3**]

Applicant : Gary K. SCHWARTZ
U.S. Serial No.: 10/693,301
Filed : October 24, 2003
Page : 2

4. L.C. Song, K.Z. Chen, J.Y. Zhu, "The effect of *Coptis chinensis* on lipid peroxidation and antioxidases activity in rats", *Chung Kuo Chung Hsi I Chieh Ho Tsa Chih* (1992 Jul) 12(7):421-3, 390. **[Exhibit 4]**
5. M. Umeda, S. Amagaya and Y. Ogiwara, "Effects of certain herbal medicines on the biotransformation of arachidonic acid: a new pharmacological testing method using serum", *J Ethnopharmacol* (1988 May-Jun) 23(1):91-8. **[Exhibit 5]**
6. G.D. Wang, Y.M. Zhang and X.Y. Xiong, "Clinical and experimental study of burns treated locally with Chinese herbs", *Chung Hsi I Chieh Ho Tsa Chih* (1991 Dec) 11(12):727-9, 709. **[Exhibit 6]**
7. W.M. Huang, J. Yan, and J. Xu, "Clinical and experimental study on inhibitory effect of sanhuang mixture on platelet aggregation", *Chung Kuo Chung Hsi I Chieh Ho Tsa Chih* (1995 Aug) 15(8):465-7. **[Exhibit 7]**
8. Y. Kobayashi, Y. Yamashita, N. Fuji, K. Takaboshi, T. Kawakami, M. Kamwamura, T. Mizukami, and H. Nakano, "Inhibitors of DNA topoisomerase I and II isolated from the *Coptis rhizomes*". *Planta Med* 61: 414-418, 1995. **[Exhibit 8]**
9. X.P. Fang, T.Z. Wang, H. Shang, H. Shuai, D. Li, and C.K. Xie, "Quantitative determination of 5 alkaloids in plants of *coptis* from china". *Chung Kuo Yao Tsa chih* 14: 33-35, 1989. **[Exhibit 9]**
10. C.W. Chi, Y.F. Chang, T.W. Cjao, S.H. Chiang, F.K. P'eng, W.Y. Lui, and T.Y. Liu, "Flowcytometric analysis of the effect of berberine on the expression of glucocorticoid receptors in human hepatoma HepG2 cells". *Life Sci* 54: 2099-2107, 1994. **[Exhibit 10]**
11. M. Fukutake, S. Yokota, H. Kawamura, A. Iizuka, S. Amagaya, K. Fukuda, and Y. Komatsu, "Inhibitory effect of *Coptidis Rhizoma* and *Scutellariae Radix* on azoxymethane-induced aberrant crypt foci formation in rat colon", *Bio. Pharm Bull* 21: 814-817, 1998. **[Exhibit 11]**

Applicant : Gary K. SCHWARTZ
U.S. Serial No.: 10/693,301
Filed : October 24, 2003
Page : 3

12. C.L. Qin, J.Y. Liu, and Z.M. Cheng, "Pharmacological studies on the effect of huanglian decoction on experimental gastric lesions in rats and antiemetic in pigeons", Chung Kuo Chung Yao Tsa Chih 19: 427-430, 1994. **[Exhibit 12]**
13. C.Y. Yeung, F.T. Lee, and H.N. Wong, "Effect of a Popular Chinese Herb on Neonatal Bilirubin Protein Binding", Biol Neonate 58: 98-103, 1990. **Exhibit 13]**
14. E. Chan, "Displacement of bilirubin from albumin by berberine", Biol Neonate (1993) 63(4):201-8. **[Exhibit 14]**
15. J.A. Marin-Neto, B.C. Maciel, A.L. Seecches, and L. Gallo, "Cardiovascular effects of berberine in patients with severe congestive heart failure", Clin Cardiol 11: 253-260, 1988. **[Exhibit 15]**
16. X. Zeng and X. Zeng, "Relationship between the clinical effect of berberine on severe congestive heart failure and its concentration in plasma studied by HPLC". Biomed Chromatogr 13: 442-444, 1999. **[Exhibit 16]**
17. X.S. Gao, "Absorptive capacity of upper gastrointestinal tract with Chinese herbal medicine", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1993 Jul) 13(7):433-5, 390. **[Exhibit 17]**
18. Y. Ozaki, H. Suzuki, and M. Satake, "Comparative studies on concentration of berberine in plasma after oral administration of coptidis rhizoma extract, its cultured cells extract and combined use of these extracts and glycyrrhizai radix extract in rats", Yakugaku Zasshi 113: 63-69, 1993. **[Exhibit 18]**
19. P. Nurse, "Universal control mechanism regulating onset of M phase nature", (Lond) 344: 503-508, 1990. **[Exhibit 19]**
20. W-C Chuang, D-S Young, L.K. Liu, and S-J Sheu, "Liquid chromatography-electrospray mass spectrometric analysis of coptidis Rhizoma", J. Chromatog 755L 19-26, 1996. **[Exhibit 20]**

Applicant : Gary K. SCHWARTZ
U.S. Serial No.: 10/693,301
Filed : October 24, 2003
Page : 4

21. C.M. Chen, H.C. Chang, "Determination of berberine in plasma, urine, and bile by HPLC", J. Chromatogr. 117-123, 1995. [Exhibit 21]
22. H. Zhang, T. Want, X. Fang, H. Shuai, and C. Xie, "Plants of coptis from tibet and yunnan", Chung Kuo Chung Yao Tsa Chih China Journal Of Chinese Materia Medica. 15: 326-328, 1990. [Exhibit 22]
23. D.L. Walker, J.M. Reid, and M.M. Ames, "Preclinical Pharmacology of bizelesin, a potent bifunctional analog of the DNA-binding antibiotic CC-1065", Cancer Chemother Pharmacol 34: 317-322, 1994. [Exhibit 23]

If a telephone interview would be of assistance in advancing prosecution of the subject application, Applicant's undersigned attorney invites the Examiner to telephone him at the number provided below.

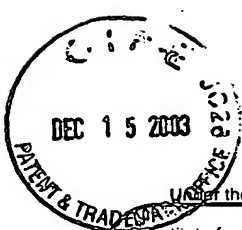
No fee is deemed necessary in connection with the filing of this Information Disclosure Statement. However, if any additional fee is required, authorization is hereby given to charge the amount of any such fee to Deposit Account No. 50-1891.

I hereby certify that this paper is being deposited this date with the U.S. Postal Service with sufficient postage for first class mail addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450

Albert Wai-Kit Chan 12/11/03
Albert Wai-Kit Chan Date
Reg. No. 36,479

Respectfully submitted,

Albert Wai-Kit Chan
Albert Wai-Kit Chan
Registration No. 36,479
Attorney for Applicant
Law Offices of
Albert Wai-Kit Chan, LLC
World Plaza, Suite 604
141-07 20th Avenue
Whitestone, New York 11357
Tel: (718) 357-8836
Fax: (718) 357-8615
E-mail: kitchanlaw@aol.com



DEC 15 2003

PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Applicati n Number 10/693,301

Filing Dat October 24, 2003

First Nam d Inventor Gary K. SCHWARTZ

Art Unit

Examiner Name

Attorney Docket Number 702-A-US

Sheet 1 of 3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	1	L. Zhang, L. Yank, X. Zheng, "A study of helicobacterium pylori and prevention and treatment of chronic atrophic gastritis", J. Tradit. Chin. Med., 17:3-9, 1997.	
	2	L.Q. Yang, M. Singh, E.H. Yap, G.C. Ng, H.X. Xu, and K.Y. Sim, "In vitro response of Blastocystis hominis against traditional Chinese medicine", J. Ethnopharmacol 55: 35-42, 1996.	
	3	S.G. Franzblau and C. Cross, "Comparative in vitro antimicrobial activity of Chinese medicinal herbs. J. Ethnopharmacol", 15: 279-288, 1986.	
	4	L.C. Song, K.Z. Chen, J.Y. Zhu, "The effect of Coptis chinensis on lipid peroxidation and antioxidases activity in rats", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1992 Jul) 12(7):421-3, 390.	
	5	M. Umeda, S. Amagaya and Y. Ogiara, "Effects of certain herbal medicines on the biotransformation of arachidonic acid: a new pharmacological testing method using serum", J Ethnopharmacol (1988 May-Jun) 23(1):91-8.	
	6	G.D. Wang, Y.M. Zhang and X.Y. Xiong, "Clinical and experimental study of burns treated locally with Chinese herbs", Chung Hsi I Chieh Ho Tsa Chih (1991 Dec) 11(12):727-9, 709.	
	7	W.M. Huang, J. Yan, and J. Xu, "Clinical and experimental study on inhibitory effect of sanhuang mixture on platelet aggregation", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1995 Aug) 15(8):465-7	
	8	Y. Kobayashi, Y. Yamashita, N. Fuji, K. Takaboshi, T. Kawakami, M. Kamwamura, T. Mizukami, and H. Nakano, "Inhibitors of DNA topoisomerase I and II isolated from the Coptis rhizomes". Planta Med 61: 414-418, 1995	
	9	X.P. Fang, T.Z. Wang, H. Shang, H. Shuai, D. Li, and C.K. Xie, "Quantitative determination of 5 alkaloids in plants of coptis from china". Chung Kuo Yao Tsa chih 14: 33-35, 1989	
	10	C.W. Chi, Y.F. Chang, T.W. Cjao, S.H. Chiang, F.K. P'eng, W.Y. Lui, and T.Y. Liu, "Flowcytometric analysis of the effect of berberine on the expression of glucocorticoid receptors in human hepatoma HepG2 cells". Life Sci 54: 2099-2107, 1994	

Examiner Signature	Date Considered
-----------------------	--------------------

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (04-03)

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/693,301
Filing Date	October 24, 2003
First Name and Inventor	Gary K. SCHWARTZ
Art Unit	
Examiner Name	
Attorney Docket Number	702-A-US

Sheet

2

of

3

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	11	M. Fukutake, S. Yokota, H. Kawamura, A. Iizuka, S. Amagaya, K. Fukuda, and Y. Komatsu, "Inhibitory effect of Coptidis Rhizoma and Scutellariae Radix on azoxymethane-induced aberrant crypt foci formation in rat colon", Bio. Pharm Bull 21: 814-817, 1998	
	12	C.L. Qin, J.Y. Liu, and Z.M. Cheng, "Pharmacological studies on the effect of huanglian decoction on experimental gastric lesions in rats and antiemetic in pigeons", Chung Kuo Chung Yao Tsa Chih 19: 427-430, 1994	
	13	C.Y. Yeung, F.T. Lee, and H.N. Wong, "Effect of a Popular Chinese Herb on Neonatal Bilirubin Protein Binding", Biol Neonate 58: 98-103, 1990	
	14	E. Chan, "Displacement of bilirubin from albumin by berberine", Biol Neonate (1993) 63(4):201-8	
	15	J.A. Marin-Neto, B.C. Maciel, A.L. Seecches, and L. Gallo, "Cardiovascular effects of berberine in patients with severe congestive heart failure", Clin Cardiol 11: 253-260, 1988	
	16	X. Zeng and X. Zeng, "Relationship between the clinical effect of berberine on severe congestive heart failure and its concentration in plasma studied by HPLC". Biomed Chromatogr 13: 442-444, 1999	
	17	X.S. Gao, "Absorptive capacity of upper gastrointestinal tract with Chinese herbal medicine", Chung Kuo Chung Hsi I Chieh Ho Tsa Chih (1993 Jul) 13(7):433-5, 390	
	18	Y. Ozaki, H. Suzuki, and M. Satake, "Comparative studies on concentration of berberine in plasma after oral administration of coptidis rhizoma extract, its cultured cells extract and combined use of these extracts and glycyrrhizai radix extract in rats", Yakugaku Zasshi 113: 63-69, 1993	
	19	P. Nurse, "Universal control mechanism regulating onset of M phase nature", (Lond) 344: 503-508, 1990	
	20	W-C Chuang, D-S Young, L.K. Liu, and S-J Sheu, "Liquid chromatography-electrospray mass spectrometric analysis of coptidis Rhizoma", J. Chromatog 755L 19-26, 1996	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

1 Applicant's unique citation designation number (optional). 2 Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.



PTO/SB/08B (04-03)

Approved for use through 04/30/2003. OMB 0651-0031

U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449/PTO

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

Complete if Known

Application Number	10/693,301
Filing Date	October 24, 2003
First Named Inventor	Gary K. SCHWARTZ
Art Unit	
Examiner Name	
Attorney Docket Number	702-A-US

Sheet	3	of	3
-------	---	----	---

NON PATENT LITERATURE DOCUMENTS

Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ²
	21	C.M. Chen, H.C. Chang, "Determination of berberine in plasma, urine, and bile by HPLC", J. Chromatogr. 117-123, 1995	
	22	H. Zhang, T. Want, X. Fang, H. Shuai, and C. Xie, "Plants of coptis from tibet and yunnan", Chung Kuo Chung Yao Tsa Chih China Journal Of Chinese Materia Medica. 15: 326-328, 1990	
	23	D.L. Walker, J.M. Reid, and M.M. Ames, "Preclinical Pharmacology of bizelesin, a potent bifunctional analog of the DNA-binding antibiotic CC-1065", Cancer Chemother Pharmacol 34: 317-322, 1994	

Examiner Signature		Date Considered	
--------------------	--	-----------------	--

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Applicant's unique citation designation number (optional). ² Applicant is to place a check mark here if English language Translation is attached.

This collection of information is required by 37 CFR 1.98. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 120 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, Washington, DC 20231.

If you need assistance in completing the form, call 1-800-PTO-9199 (1-800-786-9199) and select option 2.